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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,112	01/25/2002	Kurt Osther	45579/56876	1887

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,112	OSTHER ET AL.	
	Examin r	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sh et with th correspondenc address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-33,39-42 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-33,39-42 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 29-33, 39-42, and 52 have been considered but are moot in view of the new ground(s) of rejection.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 29-33, 39-42, and 52 recite "A cell-free cartilage membrane". The cartilage membrane was not found in the specification to be referred to as "cell-free", and does not disclose anywhere the absence of cells, benefit of having an absence of cells anywhere. In fact, the applicants entire invention seems to focus on the idea of cells growing or invading the membrane, and even discloses cells inside the membrane (pg.14, lines 32-35) and in all drawings, the membrane is in contact with the suspension of cells at the membranes surface. This is a possible new matter issue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29-33 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Vibe-Hansen et al. (USPN 5,759,190, cited by applicant in IDS). Referring to claims 29 and 52, Vibe-Hansen discloses a cell free cartilage membrane and kit (col.2, lines 35-40) comprising at least one surface part carrying a composition comprising at least one stimulation molecule, which induces a signal transduction in chondroblasts/chondrocytes and which is selected from the group consisting of collagen proteins (collagens I, II, III.; col.7, lines 1-5, 10-12; col.8, lines 43-45) and non-collageneous proteins (fibronectin and fibrinogen, col.5 lines 7-10, are both in or attached to the patch, even though they are elements of the Tisseel adhesive, and applicant has argued that they will not create a signal transduction, this in non-persuasive, because applicant has listed specifically fibronectin and fibrinogen in claim 30 to be elements which are non-collageneous proteins that induce a signal transduction, and Vibe-Hansen has disclosed the exact elements and therefore, they will inherently have the effect the applicant is claiming).

Referring to claim 30, Vibe-Hansen discloses a collagen protein being collagen II (col.8, lines 43-45, 50-51), and a non-collageneous protein being fibronectin (col.5, lines 7-10, see above).

Referring to claims 31-32, Vibe-Hansen discloses a non-immunogenic, non-toxic, biodegradable, substantially porous membrane (col.2, lines 28-35).

Referring to claim 33, Vibe-Hansen discloses the membrane being a natural or synthetic collagen type I membrane (col.7, lines 9-13).

Claims 29, 31, 32, and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Athanasiou et al. (USPN 5,876,452, cited by applicant in IDS). Referring to claims 29 and 52,

Athanasiou discloses a cell free (Athanasiou discloses cells *may* be included, although not necessary, therefore, Athanasiou's implant may be cell free, col.10, lines 13-15) cartilage membrane (implant) and kit comprising at least one surface part carrying a composition (bioactive agent) comprising at least one stimulation molecule, which induces a signal transduction in chondroblasts/chondrocytes and which is selected from the group consisting of collagen proteins, proteoglycans, and non-collageneous proteins (col.9, lines 28-49).

Referring to claims 31-32, Athanasiou discloses a non-immunogenic, non-toxic, biodegradable, substantially porous membrane (col.9, lines 19-21).

Claims 29, 31-33, and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Pachence et al. (USPN 6,080,194). Referring to claims 29 and 52, Pachence discloses a cell free cartilage membrane (12) and kit (col.1, lines 6-10; col.4, lines 28-32; Example 3; may be with or *without* cells) comprising at least one surface part carrying a composition comprising at least one stimulation molecule, which induces a signal transduction in chondroblasts/chondrocytes and which is selected from the group consisting of collagen proteins, proteoglycans, and non-collageneous proteins.

Referring to claims 31-32, Pachence discloses a non-immunogenic, non-toxic, biodegradable, substantially porous membrane (col.3, lines 33-35).

Referring to claim 33, Pachence discloses the membrane being a natural or synthetic collagen type I membrane (col.5, lines 1-2).

Claim29-33, 39-42, and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz et al. (USPN 6,251,143 B1). Referring to claims 29 and 52, Schwartz discloses a cell free (may or may not include cells, Schwartz discloses a membrane having an attachment factor and/or cell, col.4, lines 16-30; col.11, lines 9-12, therefore the cells need not be included and may be cell free) cartilage membrane (16) and kit comprising at least one surface part carrying a composition comprising at least one stimulation molecule (attachment factor), which induces a signal transduction in chondroblasts/chondrocytes and which is selected from the group consisting of collagen proteins, proteoglycans, and non-collageneous proteins (col.4, lines 16-26; col.11, lines 8-20).

Referring to claim 30, Schwartz discloses a collagen protein being collagen II, VI, IX, XI, a proteoglycan being aggrecans, decorin, fibromodulin, biglycan, and a non-collageneous protein being cryoprecipitate, fibronectin, vitronectin, fibrinogen, fibrillin, kistrin, echistatin, von Willebrand factor, tenascin, or anchorin CII (col.4, lines 16-26; col.11, lines 8-20).

Referring to claims 31-32, Schwartz discloses a non-immunogenic, non-toxic, biodegradable, substantially porous membrane (16; col.7, lines 46-48).

Referring to claim 33, Schwartz discloses the membrane (16) being a natural or synthetic collagen type I membrane (col.10, lines 58-66).

Referring to claims 39-42, Schwartz discloses the stimulation molecule comprising at least one RGD motif, a natural or synthetic protein or peptide or fusion, collagen II or fibronectin (col.4, lines 16-26; col.11, lines 8-20), and wherein the stimulation molecule (attachment factor) is attached to a support (16).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER